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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,775	10/31/2003	John J. Allen	LFS-5016	2856
27777	7590	02/02/2006	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			NGUYEN, HUONG Q	
		ART UNIT		PAPER NUMBER
				3736

DATE MAILED: 02/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/698,775	ALLEN, JOHN J.	
	Examiner	Art Unit	
	Helen Nguyen	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 31 October 2003.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-13 is/are pending in the application.
 4a) Of the above claim(s) 7-9 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-6, 10-13 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 31 October 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/31/03, 2/07/05</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species of the claimed invention: species 1, directed to a trigger mechanism including pawls; species 2, directed to a trigger mechanism including a frictional clutch; species 3, directed to a trigger mechanism including an optical relay switch; and species 4, directed to a trigger mechanism including an electrical relay switch.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1 and 11 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. During a telephone conversation with Mayumi Maeda on 01/12/06 a provisional election was made without traverse to prosecute the invention of a lance with a trigger mechanism comprising of pawls, **Claims 1-6,10-13**. Affirmation of this election must be made by applicant in replying to this Office action. **Claims 7-9** are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 10/31/03 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

4. The disclosure is objected to because of the following informalities:
Portion 210, referred to in paragraph [0024] of the specification, is not shown in Figure 2 of the drawings.

The US Patent Application, referred to in paragraph [0032] of the specification, is not disclosed.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. **Claims 1, 2, 5, 10-13** are rejected under 35 U.S.C. 102(e) as being anticipated by Sakata et al (US Pub No. 2004/0215224). In regards to **Claim 1**, Sakata et al disclose a lancing device comprising 1) a housing (2) formed with a “cylindrical member” (20) (¶0063); 2) a lancing mechanism (3) operatively attached to the housing (¶0067); 3) a pressure tip, referred to as a “cylindrical member” (8) including an “analysis sensor” (4), moveably attached to the housing for engaging a target site and creating a target site bulge (¶0080, 0081); 4) a trigger mechanism comprising of a “sensor holder” (7B) and “pivot member” (79) for detecting a target site bulge of a predetermined height and triggering an immobilization of the pressure tip with respect to the housing. Because the pressure tip is defined with the “analysis sensor” (4) and said sensor becomes immobilized at a predetermined angle, which depends upon the degree of skin bulging, the pressure tip is considered to immobilize as a whole (¶0110, 0111). Please see Figure 19 for a detailed drawing.

7. In regards to **Claim 2**, Sakata et al disclose a bias spring (83) for applying a pre-load force against the cylindrical member (8) of the pressure tip (Figure 19), as defined above. In regards to **Claim 5**, Sakata et al disclose a trigger mechanism including at least one locking pawl (7B) and at least one pawl trigger arm (79) wherein the “pivot member” (79) and “sensor holder” (7B), which includes “stopper” (77a), perform a motion-deterring function and thus are considered as pawls (¶0110). In regards to **Claim 10**, Sakata et al disclose the trigger mechanism configured to initiate lancing by the lancing mechanism once the pressure tip has been immobilized, as described previously (¶0082, 0084).

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8. In regards to **Claim 11**, Sakata et al disclose a method for lancing a target site comprising
1) providing a lancing device that includes a housing (2), a lancing mechanism (3), a pressure tip
(4, 8 as defined above), and a trigger mechanism (7B, 79) as explained for **Claim 1**;
2) contacting the pressure tip with the target site (¶0080); 3) urging the pressure tip towards the
target site, thereby creating target site bulge (¶0081) that is detected by the trigger mechanism
(7B, 79) and triggering an immobilization of the pressure tip with respect to the housing, as
described above (¶0110, 0111); 4) lancing the target site bulge with the lancet mechanism
(¶0082, 0084).

9. In regards to **Claim 12**, Sakata et al disclose the target site as a dermal tissue target site,
skin S (¶0080). In regards to **Claim 13**, Sakata et al disclose providing a lancing device that
includes a bias spring (83) for applying a pre-load force against the cylindrical member (8) of the
pressure tip, as explained previously (Figure 19).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all
obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. **Claims 3,4** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakata et al in view of Schmelzeisen-Redeker et al (US Pat No. 6589260). Sakata et al disclose a spring (83) to apply a pre-load force against the pressure tip but do not specify the specific strength of the spring. Schmelzeisen-Redeker et al disclose a lancing device with a spring that supplies a force of 10-15 N to optimally control the pressing force needed to operate the lancet (Col.7 line 58-65,

Col.8 line 26-30). Therefore, it would have obvious to one of ordinary skill in the art at the time the invention was made to modify the spring disclosed by Sakata et al to provide a force within the ranges of 3-13 N and 9-10 N, as taught by Schmelzeisen-Redeker et al, to provide a sufficient amount of force to operate the lancing device, including that necessary to create a desired target site bulge.

12. **Claim 6** is rejected under 35 U.S.C. 103(a) as being unpatentable over Sakata et al in view of Shraga (US Pub No. 2005/0038465). Sakata et al disclose a locking pawl (7B) with stopper (77a) but do not disclose the pawl having multiple ratchet teeth. Sakata et al also do not disclose the pressure tip having ratchet teeth, wherein the pressure tip is defined to include “analysis sensor” (4), which is attached to “pivot member” (79), therefore constituting pivot member as a part of the pressure tip. Shraga discloses a lancet device that uses ratchet teeth to engage pawls as an effective method to maintain the depth setting, shown in Figures 47-50 (¶0124 and 0125). Therefore, it would have obvious to one of ordinary skill in the art at the time the invention was made to modify the locking pawl (7B) and the pivot member (79) of the pressure tip, as disclosed by Sakata et al, to both include multiple ratchet teeth as further taught by Shraga, to enhance the immobilization mechanism disclosed by providing a more fitted engagement of the stopper (77a) of the locking pawl (7B) against the pivot member (79) of the pressure tip during immobilization to create a superior trigger mechanism.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bajaj et al (US Pat No. 6056765) and Perez et al (US Pub No. 20020188223) both disclose lancet devices.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is 571-272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

HQN
1/30/06



MAX F. HINDENBURG
PRIMARY PATENT EXAMINER
TECH CENTER 3700

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